REMARKS

In the outstanding Office Action, Claims 1-17 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 5,925,073 to Chastain et al. in view of U.S. Patent Number 5,683,445 to Swoyer. Claims 1, 2, and 4-13 were rejected under 35 U. S. C. 103(a) as being unpatentable over Swoyer in view of Chastain et al. In addition, Claims 1, 2, 4, 5, 6, 9, 11, and 12 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 5,387,233 to Alferness et al. Reconsideration is respectfully requested in light of the above claim amendments and the following remarks.

Applicants' claimed invention, as set forth in pending Claim 1, is directed to a coronary sinus lead that includes a lead body having exactly two non-helical bends that define substantially an s-shaped portion. The lead further includes an electrode that is located distal of the s-shaped portion and is oriented toward the vessel wall. In order to achieve the s-shaped portion, both the lead body and the internal conductor are preformed having the two non-helical bends.

It is known that a desirable lead design should satisfy two criteria. First, the lead must provide some manner of fixation so that it will not become dislodged once it is implanted. Second, the lead must provide some degree of flexibility and maneuverability to facilitate the implant procedure. Unlike the prior art cited by the Examiner, applicants' claimed lead design simultaneously achieves both criteria. By providing exactly two bends, a stylet or guidewire is relatively easily advanceable through the lead to straighten the lead during implant. In addition, by preforming both the lead body and the conductor to have the s-shaped configuration, the lead provides sufficient rigidity to prevent dislodgement, in spite of the fact that the lead only has the two bends.

In contrast, the Chastain et al. patent discloses a lead formed with a __series__ of peaks and valleys that serve to passively fix the lead within the coronary sinus. As described at column 2, lines 7-14, the lead includes "a plurality of longitudinally spaced peaks and valleys such that the lead body engages the vein wall at discrete points for inhibiting displacement of the electrode". Thus, Chastain et al. teach that in order for

the lead to prevent dislodgement, a plurality of peaks and a plurality of valleys are provided. This results in a lead that is much more difficult to implant, due to the drag on the stylet from the relatively large number of bends. Chastain et al. do not teach a lead that provides only two bends. Nor would one be motivated by the teachings of Chastain et al. to design such a lead, since the explicit teaching of Chastain et al. is that a plurality of peaks and a plurality of valleys are provided to passively fix the lead in the coronary sinus.

Moreover, by providing the large number of bends along a relatively long length of the lead, the proximal bends in Chastain et al.'s lead will be subjected to contraction at different times than the distal bends due to the asynchronous contraction profile of the ventricle. This can result in the proximal bends pulling against the distal bends, which causes an effect known as "walking out" of the lead.

Thus, providing a large number of bends along a long length of the lead is disadvantageous for at least two reasons: one, implanting the lead becomes more difficult, and two, the asynchronous nature of contraction can result in the proximal bends pulling against the distal bends, which can result in partial dislodgement or "walking out" of the lead.

The Swoyer patent discloses a coronary sinus lead having a straight body segment and a distal end region that consists of two 45-degree bends, such that an electrode at the distal tip is directed laterally for contact with the coronary tissue. Nowhere does Swoyer teach or suggest an s-shaped region to engage the coronary tissue. In fact, Swoyer does not disclose or suggest any anchoring structure that engages diametrically opposed sides of a vessel. Rather, Swoyer discloses a straight lead section 53 that contacts the vessel along one side of the vessel, as well as along the entire length of lead section 53. This design is undesirable in that not only does it engage only one side of the vessel, it also spreads the contact force over a large distance, and therefore cannot effectively stabilize the lead in a short segment of a cardiac vein. On the other hand, applicants' claimed lead provides exactly two bends that function as substantially point contacts to allow for stabilization in short segments of cardiac vein, and that also engage diametrically opposed sides of the vessel. This

disadvantage of Swoyer is highlighted by the fact that Swoyer teaches the inclusion of a separate anchoring sleeve 7 to secure the lead in place.

Thus, neither Chastain et al. nor Swoyer, whether taken alone or in combination, teach applicants' claimed structure having exactly two bends defining an s-shaped region. Both Chastain et al. and Swoyer disclose leads that have significantly more contact with the coronary sinus. Neither teaches or suggests a lead design that has a minimal number of contacts, as in applicants' claimed invention.

Similar to Chastain et al., Alferness teaches a lead design that provides a large number of contact points to ensure the lead remains in place. Alferness teaches a coiled configuration for the passive fixation, which obviously would result in continuous contact over a long length of the lead, as shown in Fig. 1. As described above in connection with Chastain et al., such a design can be relatively difficult to implant, and can result in "walking out" of the lead due to the asynchronous contraction of the heart.

Alferness does briefly allude to a "serpentine" configuration as an alternate design; however, nowhere does Alferness teach or in any way suggest to one skilled in the art a design that includes only two bends in an s-shaped configuration. Simply saying that the lead could have a "serpentine" configuration does not motivate one skilled in the art to design a lead with exactly two bends, especially when the entirety of Alferness' disclosure conveys designs that provide a large amount of contact with the coronary sinus to prevent dislodgement. As shown in Fig. 4, Alferness illustrates a significant number of contact points to achieve fixation, and would not motivate one skilled in the art to design a lead having exactly two bends. The description in Alferness suggests to one skilled in the art that in order to achieve suitable fixation, one needs to provide a large number of bends, as shown in Fig. 4 of Alferness.

CONCLUSION

In view of the foregoing, it is respectfully submitted that all of the pending claims patentably distinguish over the cited references, and a Notice of Allowance is earnestly solicited.

Respectfully submitted,

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